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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
03/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/738,455	JEGLA, TIMOTHY J.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Amendment filed 12 December 2007 has been entered in full. Claims 11 and 14 are pending. Claim 11 has been amended. Therefore, claims 11 and 14 are currently pending and the subject of this Office Action.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

4. Applicant has provided a declaration filed under 37 CFR 1.132.

Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st Paragraph, maintained

5a.35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5b. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 and 14 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility, or a well established utility. Novel biological molecules lack an established utility and must

undergo extensive experimentation to determine an appropriate specific and substantial utility. The basis for this rejection is set forth for at pg 10-16 of the Office Action mailed 12 June 2007.

The instant application discloses polypeptide of SEQ ID NO: 17 (Kv6.2). The specification asserts that, this polypeptide monomer is a member of the "Kv" superfamily of potassium channel monomers. Members of this family are polypeptide monomers that are subunits of voltage-gated potassium channels having six transmembrane regions (K=potassium, v=voltage-gated). Voltage-gated potassium channels have significant roles in maintaining the resting potential and in controlling excitability of a cell (See page 8, lines 17-27).

The specification discloses that when human Kv6.2 monomer is co-expressed in Xenopus oocytes with human Kv2.1 monomer it produces voltage gated current (page 63). However, the specification does not provide an expression profile (for example: where it is expressed) of this gene or protein. Although the specification contemplates the use of Kv6.2 in CNS related diseases (see page 12), the art published after the priority date discloses that the Kv6.2 mRNA is preferentially expressed in myocardium (Zhu et al. Receptors and Channels 6(5): 337-350, 1999, Ref AJ of PTO1449 filed 12/16/2003). In addition, the instant specification does not teach any physiologic ligands or modulators of the Kv6.2 polypeptide set forth in SEQ ID NO: 17. There is no well-established utility for specific polypeptides of Kv6.2, and the specification fails to disclose a specific and substantial utility for the claimed invention. The instant application does not disclose a specific biological role for the Kv6.2 protein or its

significance to a particular disease, disorder, or physiological process which one would manipulate for a desired physiological or clinical effect.

Applicant's arguments (12 December 2007) as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.
It is noted that at pg 6 of the Response, Applicant cites pertinent case law reviewing the Utility requirement. The Examiner takes no issue with the case law that has been cited or the holding that was found in that case law. The essential disagreement appears to be the interpretation of what constitutes a specific and substantial asserted utility, or a well established utility.

Applicant argues at pg 7 of the response (12 December 2007) that the K^+ channels comprising the claimed polypeptide monomers "have significant roles in maintaining the resting potential and in controlling excitability of a cell, " especially in the central nervous system (CNS) such as brain (see pg 8, lines 16-22, and Examples 1 and 2 of the specification).

Applicant further argues that the specification states that the sequences of these K^+ channel subunits would enable assay systems to identify compounds that specifically modulate the activity of the channels, and that these compounds *may* be used in treatment of diseases relevant to altered potassium channel activities, for example central nervous system (CNS) disorders including migraines, hearing and vision problems, psychotic disorders, seizures. Applicant also contends that the compounds identified also may be useful as neuroprotective agents, for instance, to prevent stroke (see pg 8, lines 23-27 of the specification).

Applicant argues at pg 7 of the response that the MPEP states that application show sufficient specific utility when applicants disclose a "specific biological activity" and reasonably correlate that activity to a "disease condition" (citing MPEP §2107.01 and 2107.02). Applicant asserts that the instant application discloses a disease condition, i.e., altered cell resting potential and excitability that correlates with a biological activity, i.e., the opening and closing of the claimed voltage-gated K^+ channels. Lastly, Applicant argues at pg 7 of the response that the specification demonstrates that the claimed Kv6.2 channels are expressed in tissues Kv6.2 channel activities, which may be used for treating diseases such as migraines, seizures, or other CNS disorders. Thus, Applicant asserts that the identification of the Kv6.2 polypeptide has a specific and substantial utility or "real world" use, since this discovery makes possible the routine identification of activators and inhibitors of the Kv6.2 channels which *may* be used as therapeutic agents for treating conditions caused by aberrant cell excitability in tissues expressing the Kv6.2 subunit, such as migraine and seizure.

Applicant's arguments (12 December 2007) have been fully considered but are not persuasive for the following reasons. Contrary to Applicants assertion, "altered cell excitability" is not a disease condition. While altered cell excitability may be linked to a specific disease, the instant specification does not teach any specific disease state that is associated with the claimed Kv6.2 polypeptide of SEQ ID NO: 17. This can only be accomplished through additional extensive experimentation. Whereas one could readily employ the putative Kv6.2 protein of SEQ ID NO:17 of the instant invention in an assay to identify ligands thereto and modulators thereof, the information obtained from such

assays would be of little use until one discovers the identity of those biological processes or disease conditions that are modulated by that putative Kv6.2 protein. Because the instant specification has failed to identify a biological process which has been shown to be influenced by the activation or inhibition of the putative receptor protein of the instant invention, an artisan would have no way of predicting what effects the administration of that ligand to an organism would have. If one cannot predict the effects that the administration of a ligand of the putative receptor of the instant invention is going to have on an organism, then it is unclear as to what practical or real world benefit is derived by the public from the identification of that ligand. The evidence of mere identification as a voltage-gated potassium channel subunit and expression in a tissue (see pg 62-63) is not tantamount to a showing of the role of polypeptide of SEQ ID NO: 17 in a disease/disorder, or that compounds that modulate its activity are useful in the treatment of a disease or disorder such as migraine and seizures. Therefore, the claimed protein cannot be used in a therapeutic capacity without the need for a substantial inventive contribution.There is little doubt that, after further characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention, and until it has been undertaken, Applicant's claimed invention is incomplete.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sup. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the

absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

In the Instant case, the instant specification leaves it to the practitioner to discover the identity of a disease or disorder in which the protein of the instant invention is mutated or aberrantly expressed, and to discover the nature of that mutation or aberrant expression (i.e., overexpression or under expression). Moreover, the instant Application only teaches that compounds which “modulate” the Kv6.2 channel subunit can be used to treat disorders related to altered cell excitability in the organs that express the subunit. It is readily apparent that further extensive experimentation would be required of the skilled artisan to 1) identify a specific biological role for the Kv6.2 subunit or its significance to a particular disease, disorder, or physiological process which one would want to manipulate for a desired physiological or clinical effect; and 2) determine whether compounds that inhibit the Kv6.2 subunit could be used in methods

of treatment, or whether compounds that potentiate/promote the Kv6.2 subunit could be used in treatment methods. Such additional experimentation, if needed to identify a specific utility for an invention, is precluded by the court. Since the instant specification does not disclose a "real world" use for Kv6.2, then the claimed invention is incomplete and therefore, does not meet the requirements of 35 U.S.C. §101 as being useful.

Applicant argues at pg 8 of the response (12 December 2007) that, as evidenced by the Declaration of Dr. Krafte under 37 CFR 1.132 filed (12 December 2007), "the identification of the coding sequence for Kv6.2, coupled with the demonstration of its functional expression, has a specific and substantial utility, which is credible to one of ordinary skill in the art, particularly for the purpose drug discovery" (paragraph 5 of the declaration). Applicant is arguing at pg 8 of the response that, as evidenced by the Declaration of Dr. Krafte (at paragraph 6), that several subfamilies of the Kv potassium channel family have previously been identified, which are indicated in signal transduction during various biological processes such as neuronal integration, cardiac pacemaking, muscle contraction, hormone secretion, cell volume regulation, lymphocyte differentiation and cell proliferation. It is argued by the Applicant that based on the tissue-specific pattern of expression (expressed in CNS) of Kv6.2 , an artisan would reasonably believe that these channels can serve as therapeutic target for treating CNS disorders such as migraines, hearing and vision problems, psychotic disorders and seizures., and thus identification of human Kv6.2 coding sequence (instant invention is drawn to the polypeptide of Kv6.2) not the coding sequence) makes it possible to screen for activators and inhibitors of Kv6.2 potassium channels. It is also argued at

pg8 of the response that the ability to functionally express the channels is very important in a modern drug discovery environment and allows pharmaceutical researchers to identify compounds that directly affect the channel activity. Applicant further asserts that these same compounds can then be tested in other comparable functional assays to assess selectivity and determine off-target activity and the potential for side effects. Applicant argues at pg 9 of the response that such activators or inhibitors can be used for treating conditions such as those named above and as such the present invention has a specific and real-world use. Applicant argues at pg 9 of the response that KCNQ2 is an example of a potassium channel as a target for therapeutic purposes. Loss of function mutations of KCNQ2 have been shown to cause a form of epilepsy and the KCNQ2 channels have been targets for drug discovery programs for a number of years.

Applicant argues at pg 9 of the response that, as evidenced at pg 3 of the declaration, that Dr. Krafte points out that it is well known in the art that once an ion channel has been identified, modulators of this channel can be routinely identified based on the coding sequence of the ion channel, functional expression, and method for activation of the channel. Further, Applicant argues at pg 9 of the response that, as evidenced at pg 3 of the declaration, that Dr. Krafte points out that there are known instances where modulation of an ion channel is useful for treating a specific disease even though the ion channel itself may not directly cause a disease, and therefore, it is perfectly reasonable to expect that the targeting of Kv6.2 channel, a voltage gated potassium channel that is highly expressed in the brain and is believed to play a role in

regulating the biological functions of CNS, is an appropriate strategy for treating neurological disorders, whether or not such abnormality is directly caused by altered Kv6.2 channel activity.

Applicant's arguments and the declaration under 37 CFR 1.132 (filed 12 December 2007) have been fully considered but are insufficient to overcome the rejection of claims 11 and 14 based on 35 U.S.C. § 101 as set forth in the previous Office Action. It is noted that Applicant has not provided any evidence or reference of record to substantiate the allegation that the KV6.2 protein set forth as SEQ ID NO: 17 is involved in any disease or disorder, or that molecules that interact with it or modulate its activity can be used to treat any disease or disorder.

> It must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979).

Furthermore, while the Examiner agrees that it is credible that the Kv6.2 polypeptide of SEQ ID NO: 17 is a subunit of a voltage-gated potassium channel, its identification as such is not sufficient to establish either a well-known, or a specific and substantial utility. Basic research is still required to study the properties and activity of theKv6.2

polypeptide. The specification of the instant application does not disclose the specific biological function of the Kv6.2 protein. The fact that basic research is required to establish the physiological role of the human Kv6.2 subunit simply confirms that the instant invention was not completed as filed, and therefore clearly lacks utility in currently available form.

Although, Applicant argues that several subfamilies of the Kv potassium channel family have previously been identified, which are indicated in signal transduction during various biological processes such as neuronal integration, cardiac pacemaking, muscle contraction, hormone secretion, cell volume regulation, lymphocyte differentiation and cell proliferation, there is no evidence provided in the specification to indicate that Kv6.2 is involved in such diverse physiological activities. Furthermore, whereas the identification of modulators of the putative Kv6.2 protein of SEQ ID NO: 17 of the instant invention in an assay may be routine, the information obtained from such assays would be of little use until one discovers the identity of those biological processes moderated by that putative Kv6.2 protein. Because the instant specification has failed to identify a biological process which has been shown to be influenced by the activation or inhibition of the putative Kv6.2 protein of the instant invention, an artisan would have no way of predicting what effects the administration of that ligand to an organism would have. If one cannot predict the effects that the administration of a ligand of the putative receptor of the instant invention is going to have on an organism, then it is unclear as to what practical or real world benefit is derived by the public from the identification of that ligand. In the Instant case, the instant specification leaves it to the practitioner to

discover the identity of a disease or disorder in which the protein of the instant invention is aberrantly expressed, and to discover the nature of that aberrant expression (i.e., overexpression or under expression). There is no evidence to indicate that Kv6.2 is involved migraines, hearing and vision problems, psychotic disorders and seizures.

It is further noted that contrary to the assertion that the Kv6.2 is specifically expressed in the CNS, the specification only discloses that Kv6.2 was cloned by RTPCR using whole brain, there is no indication as to the expression of this protein in brain or other CNS tissues. In addition, post filing art of Zhu et al.(1999), teaches that that Kv6.2 mRNA is expressed in the heart, liver skeletal muscle, kidney and pancreas. Furthermore, the evidence of mere identification as a voltage-gated potassium channel and expression in a tissue is not tantamount to a showing of a role of polypeptide of SEQ ID NO: 17 in a disease/disorder or that compounds that modulate its activity are useful in the treatment of a disease or disorder. Unlike the KCNQ2 potassium channel, whose loss of function mutation has been shown to cause epilepsy and the target of drug discovery program, KV6.2 protein (over expression or under expression) has not been shown to be involved in any disease. Therefore, neither the claimed protein nor compounds that modulate its activity can be used in a therapeutic capacity without the need for a substantial inventive contribution.

With respect to Applicant's assertion that "there are known instance where modulation of an ion channel is useful for treating a specific disease even though the channel itself may not cause the disease", the examiner maintains that neither the Declaration nor the Applicant has provided any evidence or reference of record to

substantiate the allegation that the Kv6.2 protein of SEQ ID NO: 17 is involved in any disease or disorder, or that molecules that interact with it or modulate its activity can be used to treat any disease or disorder, even if, *arguendo,* the claimed Kv6.2 subunit need not be directly involved in that particular disease.

Applicant argues at pg 10-11 of the response (filed 12 December 2007) that the Examiner has not provided objective reasons that are proper or sufficient to rebut the presumption of proper utility under 35 U.S.C. §101 (citing MPEP §2107.02). These arguments are not found to be persuasive. In the previous Office Actions, the Examiner made a *prima facie* showing that the claimed invention lacks utility and provided sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. The truth, or credibility, of the assertion of utility has not been questioned. Rather, the rejection sets forth that the assertion of utility is not specific or substantial. Essentially, Applicant has not provided sufficient evidence to demonstrate that the claimed nucleic acid of the instant application is supported by a specific and substantial asserted utility or a well-established utility. It is noted that M.P.E.P. 2107.01 states:

> Deficiencies under the "useful invention" requirement of 35 U.S.C. 101 will arise in one of two forms. The first is where it is not apparent why the invention is "useful." This can occur when an applicant fails to identify any specific and substantial utility for the invention or ***fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention***. Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966); In re Ziegler, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993). The second type of deficiency arises in the rare instance where an assertion of specific and substantial utility for the invention made by an applicant is not credible (emphasis added).

In the instant case, the instant specification leaves it to the skilled artisan to 1) identify a specific biological role for the Kv6.2 subunit or its significance to a particular disease, disorder, or physiological process which one would want to manipulate for a desired physiological or clinical effect; and 2) determine whether compounds that inhibit the Kv6.2 subunit could be used in methods of treatment, or whether compounds that potentiate/promote the Kv6.2 subunit could be used in treatment methods.

Applicant argues at pg 11 of the response (filed 12 December 2007) that the reference of Zhu et al. (cited in the previous Office Action) observation that Kv6.2 is expressed in the myocardium does not contradict Applicant's assertion that Kv6.2 is involved in the CNS disorders. Applicant also submits that because human Kv6.2 was cloned from human whole brain, it is clearly expressed in the brain tissue.

Applicant's argument is not persuasive because like the instant Kv6.2 cDNA, Zhu et al. also isolated the cDNA from brain library. However, the expression profile clearly indicates that Kv6.2 mRNA was expressed in the heart, liver skeletal muscle, kidney and pancreas (Figure 4, Zhu et al.). This observation clearly contradicts Applicant's observations.

Applicant also argues at pg 11-13 of the response (filed 12 December 2007) that the references cited by the Examiner (Hugnot et al., Castellano et al., and Ottschytsch et al.) only offer general discussions of the diverse structures and functions of potassium channels but do not pertain to the Kv6.2 subunit, and therefore are neither proper nor sufficient to rebut the presumption of patentable utility under 35 U.S.C. §101.

Applicant's arguments (filed 12 September 2007) have been fully considered but are not persuasive for the following reasons. The Hugnot et al., Castellano et al., and Ottschytsch et al. references were cited by the Examiner to demonstrate that while it is credible that the Kv6.2 polypeptide of SEQ ID NO:17 is subunit of a voltage-gated potassium channel, its identification as such is not sufficient to establish either a well-known, or a specific and substantial utility. The art teaches that there is a great diversity of voltage-gated K^+ channels, having different biophysical, regulational, and pharmacological properties (Hugnot et al. EMBO J. 15(13):3322-3331, 1996; cited by the Examiner in a previous Office Action). The art also teaches that thus far, 19 functional Kv α-subunits and 10 silent (i.e., regulatory) subunits have been discovered, and that despite the large number of these subunits, their exact physiological role is still poorly understood mainly because of the difficulty in recognizing a silent subunit in isolated cells or in tissue (Ottschytsch et al. Proc. Natl. Acad. Sci. USA. 99(12):7986-7991, 2002; cited by the Examiner in a previous Office Action). While the references previously cited by the Examiner do not specifically address the claimed Kv6.2 subunit, it is noted that the instant application does not teach any physiologic ligands or functional characteristics of the Kv6.2 polypeptide set forth in SEQ ID NO: 17, nor does it disclose a specific biological role for the Kv6.2 protein or its significance to a particular disease, disorder, or physiological process which one would manipulate for a desired physiological or clinical effect. Moreover, Applicant has not provided any evidence or reference of record to substantiate the allegation that the Kv6.2 protein set forth as SEQ ID NO: 17 is involved in any disease or disorder, or that molecules that interact with it or

modulate its activity can be used to treat any disease or disorder. Thus, although the conserved K^+ selective pore region and S4-S6 domains allows identification of such as a voltage-gated potassium channel subunit, mere homology is not accepted by those of skill in the art as being predictive of function. Utility must be in readily available form.

Furthermore, whereas one could readily employ the putative Kv6.2 protein of SEQ ID NO:17 of the instant invention in an assay to identify ligands thereto and modulators thereof, the information obtained from such assays would be of little use until one discovers the identity of those physiological processes moderated by that putative Kv6.2 protein. Because the instant specification has failed to identify a physiological process which has been shown to be influenced by the activation or inhibition of the putative receptor protein of the instant invention, an artisan would have no way of predicting what effects the administration of that ligand to an organism would have. If one cannot predict the effects that the administration of a ligand of the putative receptor of the instant invention is going to have on an organism, then it is unclear as to what practical or real world benefit is derived by the public from the identification of that ligand.

Applicant argues at pg 13-14 of the response (filed 12 December 2007) that the claimed Kv6.2 channels are fully characterized both structurally and functionally, and reviews the PTO's "Revised Interim Utility Guidelines Training Materials" to support this argument.

Applicant's arguments (filed 12 December 2007) have been fully considered but are not persuasive for the following reasons. The Examiner does not agree with the

comparison given. The fact pattern presented in Example 8 of the "Guidelines" is not analogous to the Instant Application. Whereas enzymes have a well-established utility, and XYZ is a well-known enzyme, the claims in the Instant Application are drawn to a novel, uncharacterized subunit of a voltage-gated potassium channel, which does not have a well-established utility. MPEP 2107.02 II.B states, "[A]n invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible". In the instant case, the specification teaches that compounds which "modulate" the Kv6.2 subunit can be used to treat disorders related to altered cell excitability in the organs that express the subunit. It is readily apparent that further extensive experimentation would be required of the skilled artisan to 1) identify a specific biological role for the Kv6.2 subunit or its significance to a particular disease, disorder, or physiological process which one would want to manipulate for a desired physiological or clinical effect; and 2) determine whether compounds that inhibit the Kv6.2 subunit could be used in methods of treatment, or whether compounds that potentiate/promote the Kv6.2 subunit could be used in treatment methods. Since further research is required to identify or reasonably confirm a "real world" use, a person of ordinary skill in the art clearly would not immediately appreciate why the invention is "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility.

Applicant argues at pg 14 of the response that this application is a continuation of 09/719919, which has matured into U.S. Patent No. 6,680,180, and to maintain the utility rejection in this case would create a significant inconsistency in the PTO practice. In response, the Examiner maintains that the current rejection is in compliance with the most currently-published version of the Utility Guidelines which require that all biological inventions must have credible, specific and substantial ("real world") utility. Additionally, each Patent Application is examined on its own merits. The invention that was deemed allowable in one patent has no bearing on this application.

The Examiner has fully considered all evidence of record and has responded to each substantive element of Applicant's response.

Claim Rejections - 35 USC § 112, 1st Paragraph

Claims 11 and 14 remain rejected under 35 U.S.C. 112, first paragraph for reasons set forth at pg 16 of the previous Office Action (mailed 11 June2007). Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention

Conclusion

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/
Primary Examiner, Art Unit 1647

JS
Art Unit 1647
March 11th, 2008